

Notice of Allowability

Application No.

10/010,729

Examiner

DANIEL KOLKER

Applicant(s)

RODRIGUEZ ET AL.

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/2/08.
2. ☒ The allowed claim(s) is/are 42,43,73 and 91-95.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20080807</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>6/2/08</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/Daniel E. Kolker, Ph.D./
Patent Examiner, Art Unit 1649
August 13 2008

DETAILED ACTION

1. The remarks and amendments filed 2 June 2008 have been entered. Claims 42 – 43, 73, and 91 - 95 are pending and under examination.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 June 2008 has been entered.

Withdrawn Rejections and Objections

3. The rejection under 35 USC 112, first paragraph for lack of enablement commensurate in scope with the claims is withdrawn. At pp. 8 - 9 of the remarks filed 2 June 2008, applicant's representative has indicated that the deposit was made with a recognized depository (ATCC) under the terms of the Budapest Treaty and has indicated that all restrictions on availability of the deposit will be irrevocably removed upon granting of the patent.

Examiner's Amendment

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in telephone interviews with Christine Dietzel on 7 August 2008 and 13 August 2008.

5. In the Specification:

The paragraph beginning at p. 9 lines 13 has been re-written as follows:

- - The present invention thus relates to the monoclonal antibody sHIgM22 (LYM22), monomers thereof, active fragments thereof, and natural or synthetic antibodies having the characteristics of sHIgM22. Recombinant antibodies derived from sHIgM22 are further contemplated and are provided herein. An sHIgM22 (LYM22) antibody myeloma has been

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deposited as Accession No. PTA-8671 with American Type Culture Collection (ATCC), 10901 University Blvd., Manassas, VA 20220-2209. The invention provides antibodies comprising a polypeptide having an amino acid sequence corresponding at least in part to a sequence selected from FIGURE 35 (SEQ ID NO:8, 7) and FIGURE 36 (SEQ ID NO:10, 9), and active fragments thereof. Recombinant or synthetic antibodies derived or based therefrom and corresponding at least in part to a sequence selected from SEQ ID NO:8, 7, 10, and 9 are further included in the present invention. - - -

In the paragraph beginning at p. 39 line 28, delete the word "ATTC" and replace with - - ATCC - - -

6. In the claims:

In claim 42, line 3, insert the word - - an - - - between the words "of" and "antibody".

In claim 42, line 6, delete the word "active".

In claim 43, line 1, insert the word - - an - - - between the words "comprising" and "isolated".

Claim 73 has be re-written as follows:

- - A pharmaceutical composition comprising a pharmaceutically acceptable carrier, vehicle, or diluent and an amount of an isolated antibody polypeptide capable of binding oligodendrocytes and capable of inducing remyelination produced by the method of

(a) introducing a vector comprising a DNA molecule comprising a DNA sequence encoding an antibody polypeptide having a heavy chain sequence comprising the amino acid sequence set out in FIGURE 35 (SEQ ID NO:7) and a light chain sequence comprising the amino acid sequence set out in FIGURE 36 (SEQ ID NO:9) into a suitable host cell;

(b) culturing the resulting host cell so as to produce the polypeptide;

(c) recovering the polypeptide produced in step (b); and

(d) purifying the polypeptide recovered in step (c). - - -

In claim 91, line 5, delete the word "active"

In claim 92, line 2, replace "heavy and light chain" with - - heavy chain and a light chain - - -

In claim 93, line 2, replace "heavy and light chain" with - - heavy chain and a light

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chain - - -

Claim 94 has been re-written as follows:

- - An isolated monoclonal antibody capable of binding oligodendrocytes and capable of inducing remyelination selected from the group consisting of mAb sHlgM22 (LYM 22) antibody (ATCC Accession No. PTA-8671), IgM monomers thereof, Fab, Fab', F(ab')₂ or F(v) fragments thereof. - - -

Status of claims

7. Claims 42 – 43, 73, and 91 – 95 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./

Patent Examiner, Art Unit 1649

August 13, 2008